

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, New York, 11433 (718)340-7000; Fax (718)662-5661  Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 05/18/2016-06/10/2016
	FEI NUMBER 3005287250

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** Hymie Aruch, RPh, Pharmacy Manager

FIRM NAME Region Care, Inc. (Northwell Health)	STREET ADDRESS 200 Community Drive
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CITY, STATE AND ZIP CODE Great Neck, New York, 11021	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Products
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

a. Smoke studies, performed by an outside vendor (b) (4), are not conducted under dynamic conditions that simulate routine aseptic operations. Consequently, there is no assurance that uninterrupted unidirectional laminar airflow is maintained during aseptic operations.


b. The HVAC returns in Cleanroom (b) (4) were observed to be obstructed by wire racks containing drug components and other supplies, as well as by garbage cans.

2. Drugs products purporting to be sterile and pyrogen-free are not laboratory tested to determine conformance with such requirements.

Specifically,

Sterile drug products prepared from non-sterile starting materials (e.g. morphine, hydromorphone, bupivacaine, and baclofen) are not tested for sterility and bacterial endotoxins (pyrogens) prior to release.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Robert C. Steyert, Investigator	DATE ISSUED 06/10/2016
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3. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a. Work surfaces, inside the ISO-5 workstations, are not sampled at least daily during periods of production. For example, review of the "(b) (4) Compounding Activity (b) (4) Log" found there was no such testing on the following days: 05/05/2016, 05/09/2016, 05/10/2016, 05/12/2016, 05/16/2016, and 05/19/2016. However, review of the prescription log indicated sterile drug products were prepared on each of these days.

b. Viable air sampling is not performed at least once daily on days of aseptic operations.

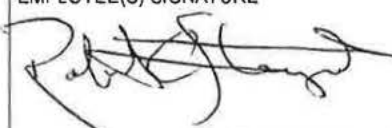
c. Magnehelic gauges (manometers) used for monitoring pressure differentials between classified rooms, including the ISO-7 classified cleanroom (which houses ISO-5 classified workstations) and the ISO-7 classified anteroom are not calibrated.

4. Laboratory controls do not include a determination of conformance to appropriate specifications for drug products.

Specifically,

There are no written procedures requiring the performance of visual checks of all sterile drug products for clarity, discoloration or particulates. Furthermore, there is no documentation to support this practice is actually being performed.

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5. Routine calibration of equipment is not performed according to a written program designed to assure proper performance.

Specifically,

(b) (4), used to monitor temperature in the ISO-7 classified ante-room and the walk-in refrigerator (used to store drug products) are not calibrated. A sticker on each of the (b) (4) indicates they were last calibrated "03/2014."

6. Clothing of personnel engaged in compounding of sterile drug products is not appropriate for the duties they perform.

Specifically,


Sterile gowns worn by operators preparing sterile drug products are reused throughout the day (i.e. they are not immediately discarded when doffed).

7. There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

On at least two occasions, environmental monitoring excursions involving the detection of "single colony" growth from (b) (4) surface and (b) (4) floor samples, respectively were documented and investigated. However, these investigations were inadequate in that:

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- Remedial cleaning and retesting is not documented as being performed.  
 - They did not include an assessment to determine what compounding activities were occurring at the time and location of the excursion to identify any potentially adverse impact on drug product quality.  
 -The "Actions Taken" section of the Incident Reports state "(b) (4)"  
 " However, there is no documentation to support this was actually performed.

8. Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

- a. The (b) (4) divider separating the LAFW (laminar airflow workstation) and (b) (4) is cleaned only (b) (4).
- b. An operator was observed dry mopping the floor of the ISO-7 classified ante-room, then enter the more critical ISO-7 classified clean room and continue mopping the floor without changing the mop head; instead of working from the greater to lesser critical area.
- c. Cleaning procedures are deficient in that the contact time for disinfectants such as (b) (4) are not defined in written procedures or documented in cleaning records.

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